

Package Leaflet: Information for the Patient
Diclofenac 75 mg / 3 ml Solution for Injection
Diclofenac Sodium

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is **Diclofenac 75mg / 3ml Solution for Injection**. It will be referred to as **Diclofenac Injection** for ease hereafter.

What is in this leaflet:

1. What **Diclofenac Injection** is and what it is used for
2. What you need to know before you are given **Diclofenac Injection**
3. How you are given **Diclofenac Injection**
4. Possible side effects
5. How to store **Diclofenac Injection**
6. Contents of the pack and other information

1. What Diclofenac Injection is and what it is used for

Diclofenac Injection is provided as a solution for injection, containing 75 mg Diclofenac sodium in 3 ml, to be given by intramuscularly (into a muscle) or intravenously (into a vein) as an infusion.

Diclofenac Injection is indicated for the treatment of painful conditions, such as kidney stone pain, osteoarthritis (degeneration of joints) and rheumatoid arthritis (inflammation of joints), back pain, gout (formation of crystals in joints), injuries and fractures in children aged over 12 years, adults and older patients.

2. What you need to know before you are given Diclofenac Injection

You should not be given Diclofenac Injection

- if you are allergic to of Diclofenac Injection or any of the other ingredients of Diclofenac Injection (listed in section 6)
- if you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in stools or black, tarry stools)
- if you have had any allergic reaction to ibuprofen, aspirin, or other NSAIDs (including difficulty in breathing, runny nose, swelling of the face or throat, or rash)
- if you have asthma
- if you have kidney or liver problems.
- if you are dehydrated or have recently lost a lot of blood

- if you have severe heart failure
- if you have a condition where you don't stop bleeding normally (such as haemophilia)
- if you have had a stroke
- if you are taking other non steroidal anti-inflammatory drugs
- if you are taking anticoagulant drugs (medicines for preventing blood clots, such as heparin and warfarin)
- if you are more than 6 months pregnant
- if you are taking medicines known as SSRIs used to treat depression.
- if you have been told by your doctor that you have an intolerance to some sugars
- if you have had stomach or bowel problems after you have taken other NSAIDs.
- if you have established heart disease and /or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- if you are breast-feeding

Warnings and precautions

Talk to your doctor, nurse or pharmacist before you are given Diclofenac Sodium :

- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- If you suffer from any of the following: blood abnormalities, bleeding conditions, Crohn's disease, inflammation of the colon.
- If you have a history of any of the following: stomach or bowel ulcers, vomiting of blood or black, tarry faeces and Gastro-intestinal ulcers
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms. Because it is an anti-inflammatory medicine, diclofenac may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking diclofenac.
- If you have heart, kidney or liver problems, or having medicines to increase urine volume such as diuretics, your doctor may monitor your kidney function.
- If you have kidney, liver or heart problems.
- If you are pregnant.
- If you have a history of high blood pressure and/or heart failure.
- If you suffer from or have previously suffered from asthma.
- If you suffer from systemic lupus erythematosus or mixed connective tissue disorders.
- If you are an older patient.
- If you have had or are about to have major surgery.
- If you suffer from any blood or bleeding disorder.

Children

Diclofenac Injection is not recommended for use in children.

Older people

Older people have increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSRIs) or anti-platelet agents such as aspirin.

Other medicines and Diclofenac Injection

Tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes any herbal products or medicines bought without a prescription.

- Digoxin (used to treat heart problems)
- Lithium (used to treat mental illness)
- Antibiotics called quinolones (such as ciprofloxacin)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Methotrexate (used for some inflammatory diseases and cancers)
- Drugs that can increase your risk of bleeding, sometimes given if you have heart problems, such as dipyridamole or clopidogrel
- Diuretics (water tablets)
- Medicines to treat high blood pressure
- Mifepristone, used to terminate pregnancy (including if you have taken it within the last 12 days)
- Medicines to treat diabetes
- Oral steroids (an anti-inflammatory drug)
- Steroids
- Zidovudine (treatment of HIV infection)
- Phenytoin (medicines to treat epilepsy)
- Colestipol and cholestyramine (medicines to lower cholesterol level)
- CYP2C9 inhibitors: e.g Sulfapyridine and voriconazole
- Other NSAIDs (for painful or inflammatory conditions) including COX2 inhibitors
- Medicines known as SSRIs used to treat depression, such as paroxetine or fluoxetine
- Medicines used to treat heart conditions or high blood pressure for example beta-blockers or ACE inhibitors.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Diclofenac Injection should only be used during pregnancy when your doctor decides the benefits to you are greater than any possible risk to the unborn baby.

Do not take **Diclofenac Injection** during the last 3 months of pregnancy as it may affect your baby's circulation and kidneys.

Breast-feeding

Do not take **Diclofenac Injection** during breast-feeding as diclofenac passes into the breast milk in small amounts.

Fertility

Taking **Diclofenac Injection** may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

Driving and using machines:

Diclofenac Injection may make you feel drowsy or dizzy, or cause headaches or problems with vision. If you are affected, do not drive or operate machinery.

Diclofenac Injection contains less than 1 mmol (23 mg) sodium per 3ml i.e. essentially sodium-free.

Diclofenac Injection contains sodium metabisulphite which can cause severe allergic reactions, especially in patients with a history of asthma or other allergies.

3. How you are given Diclofenac Injection

Diclofenac Injection can be given by deep injection into the large muscle of the buttock. The usual dose is one ampoule once daily. One ampoule twice daily may be required in severe cases, the second dose being injected into the buttock muscle on the other side.

The injection should not be given for more than 2 days. For colicky pain from the kidney area the dose is one ampoule injected into the buttock muscle and this dose may be repeated after 30 minutes if necessary.

The total dose in one day should not exceed 150mg (two ampoules).

Your doctor may decide on smaller doses if you are:

- an older person
- frail
- or you have a low body weight

If you are given more Diclofenac Injection than you should

If you think you have been given too much Diclofenac Injection tell your doctor or nurse straight away.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side-effects although not everybody gets them.

Some side effects can be serious and you should tell your doctor immediately if you notice the following:

- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering
- Wheezing or shortness of breath (bronchospasm)
- Swollen, face, lips, hands or fingers
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance.
- If you are bruising more easily than usual or have frequent sore throats or infections

The following side effects have also been reported:

Common (affects less than 1 in 10 people)

- Stomach pain
- Heartburn
- nausea (feeling sick)
- Vomiting (being sick)
- Diarrhoea
- Indigestion
- Wind
- Loss of appetite
- Headache
- Dizziness
- Vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood.
- Injection site reactions, symptoms include redness, swelling, change in the skin colour or texture

Rare (affects less than 1 in 1,000 people)

- Asthma including shortness of breath
- Diarrhoea with blood in it or bleeding from the back passage
- Blood in vomit or black, tarry faeces
- Liver function disorders, including hepatitis and jaundice.
- Injection site necrosis (dead skin and tissue around the injection site)
- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in older patients)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Somnolence (sleepiness)
- Urticaria (raised, itchy rash)
- Shock (symptoms of which include weak and rapid pulse, confusion, weakness or low blood pressure)
- Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light Headedness)
- Fluid retention, symptoms of which include swollen ankles

Very rare (affects less than 1 in 10,000 people)

- Hearing loss or impairment
- Tinnitus (ringing in the ears)
- Blurred or double vision
- Visual disturbance
- Formation of pus (abscess) at the injection site
- Disturbances in sensation
- Tingling or numbness in the skin (Paraesthesia)
- Serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome and other skin rashes (erythema multiforme, photosensitivity reaction)
- Taste changes
- Tremor
- Disorientation
- Memory impairment
- Depression

- Insomnia (sleeplessness)
- Nightmares
- Irritability (mood changes)
- Anxiety
- Psychotic disorder (mental disorders)
- Fits (convulsions)
- Constipation
- Hair loss
- Blistering of skin
- Recurring skin rashes
- Swelling of skin (including angioneurotic oedema with face oedema)
- Itching
- Inflammation of skin (**Eczema**)
- Red or purple discolorations on the skin (**Exfoliative dermatitis**)
- Severe upper abdominal pain
- Lower gut disorders (including inflammation of the colon)
- Narrowing of the bowel (which leads to intestinal obstruction)
- Worsening of ulcerative colitis (ulcers in the colon) or Crohn's disease which is characterized by abdominal pain
- Mouth ulcers
- Inflammation of the tongue
- Inflammation of the inside of the mouth or lips
- Oesophageal disorder characterized by difficulty in swallowing
- Hypertension (high blood pressure)
- Hypotension (low blood pressure)
- Aseptic meningitis (fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light)
- Inflammation of blood vessels (vasculitis)
- Kidney or liver disorders
- Presence of blood or protein in the urine
- Death of kidney cell and inflammation of the kidney
- An unexpected change in the amount of urine produced and/or its appearance which may be made worse by exposure to sunlight
- Inflammation of the pancreas
- Increased risk of heart attack or stroke
- Chest pain
- Heart disorders, including congestive heart failure
- Blood disorders (including anaemia).
- Palpitations (fast or irregular heart beat)
- Inflammation of the lung (pneumonitis)
- Fever
- Back pain

Not known: frequency cannot be estimated from the available data

- Confusion
- Hallucinations
- Disturbances of sensation
- Impotence
- Optic neuritis (inflammation of the nerves in the eye)
- Malaise (General feelings of being unwell, weakness)

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist, This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diclofenac Injection

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Keep the container in the outer carton in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Once opened, any unused liquid should be discarded.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 .Contents of the pack and other information

What Diclofenac Injection contains

The active substance is Diclofenac sodium.

The other ingredients of the each ampoule are mannitol, propylene glycol, benzyl alcohol, sodium metabisulphite, sodium hydroxide, water for injection.

What Diclofenac Injection looks like and contents of the pack

Diclofenac Injection is available in 3 ml Type I glass ampoules packaged in a carton
There are 10 ampoules per carton.

Marketing authorisation holder

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